K011159

Bisco,Incorporated
1100 W. Irving Park Road
Schaumburg, IL., 60193
510K Submission

JUN - 8 2001

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name: **ONE-STEP PLUS**
Common Name: **Universal Dental Adhesive**
Classification Name: **Resin Tooth Bonding Agent**
21 CFR 872.3200

Description of Applicant Device:
A filled dental adhesive formulated to adhesively bond to the hard tissues of the oral cavity namely enamel and dentin

Intended Uses of Applicant Device:
- Dentin-enamel primer/bonding agent for direct composite restorations.
  a. bonding to enamel b. bonding to dentin
- Indirect composite restorative luting system
- Porcelain veneer luting system
- Bonding composite to composite
- Bonding composite to metal/amalgam
- Adhesive amalgam restoration
- Bonding fresh amalgam to existing amalgam
- Bonding luting cements to dentin/enamel
- Bonding pit and fissure sealants to enamel
- Pit and fissure sealant

Predicate Device:
K 945604 ECLIPTOMER

Scientific Concepts and Significant Performance Characteristics:

	ECLIPTOMER	ONE-STEP PLUS
INTENDED USE:	A dental adhesive formulated to adhesively bond to the hard tissues of the oral cavity namely enamel and dentin	A filled dental adhesive formulated to adhesively bond to the hard tissues of the oral cavity namely enamel and dentin
PRODUCT DESCRIPTION:	Light- cured, low viscosity liquid.	Light- cured, low viscosity yellow liquid.
CHEMICAL COMPONENT:	Resin Based	Filled Resin Based

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510k) SUMMARY, continued

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Side by side comparisons of ONE-STEP PLUS to the predicate device ECLIPTOMER clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Comparative testing was conducted for ECLIPTOMER and ONE-STEP PLUS. Based on the results, it was concluded that ONE-STEP PLUS performs as well as the predicate device, ECLIPTOMER, and therefore has proven its safety and efficacy.

Cyndy Oris
Manager, Regulatory Affairs
1-800-BIS-DENT or 847-534-6146
Fax: 847-534-6396

April 24, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Ms. Cyndy Oris
Regulatory Affairs Manager
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K011159
Trade/Device Name: One-Step® Plus
Regulation Number: 872.3275
Regulatory Class: II
Product Code: EMA
Dated: April 10, 2001
Received: April 11, 2001

Dear Ms. Oris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BISCO, INC., 1100 W. Irving Park Road
Schaumburg, IL. 60193

Indications for Use

510(k) Number (if known): ~~K043604~~ K011159

Device Name: ONE-STEP® PLUS

Indications for Use:

A filled dental adhesive formulated to adhesively bond to the hard tissues of the oral cavity namely enamel and dentin

Principle Uses:

- Dentin-enamel primer/bonding agent for direct composite restorations.
  a. bonding to enamel b. bonding to dentin
- Indirect composite restorative luting system
- Porcelain veneer luting system
- Bonding composite to composite
- Bonding composite to metal/amalgam
- Adhesive amalgam restoration
- Bonding fresh amalgam to existing amalgam
- Bonding luting cements to dentin/enamel
- Bonding pit and fissure sealants to enamel
- Pit and fissure sealant

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over- the- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K011159